NOV 6 2012

SECTION 5

510(k) SUMMARY

In Compliance with 21 CFR 807.92

Submitter Information

Name:	Semprus BioSciences Corporation
Address:	One Kendall Square Building 1400 West Cambridge, MA 02139-1673 U.S.A.
Telephone Number:	617.577.7755
Contact Person:	Gregory Haas
Telephone Number:	610.698.5811
Fax Number:	617.577.7756
Email:	Gregory.Haas@semprusbio.com

Date Prepared:	November 2, 2012

Device Name

Device Trade Name:	Nylus™ PICC
Common Name:	Peripherally Inserted Central Catheter (PICC)
Classification:	Sec 880.5970 Percutaneous, implanted, long-term intravascular catheter
Product Code:	LJS
Classification Panel:	80, General Hospital and Personal Use Device Panel

Predicate Devices

Device Trade Name:	Synergy™ CT PICC
Common Name:	Peripherally Inserted Central Catheter (PICC)
Classification:	Sec 880.5970 Percutaneous, implanted, long-term intravascular catheter
510(k) Number:	K101329
Product Code:	LJS

Device Trade Name:	Zeus™ CT PICC
Common Name:	Peripherally Inserted Central Catheter (PICC)
Classification:	Sec 880.5970 Percutaneous, implanted, long-term intravascular catheter
510(k) Number:	K083763
Product Code:	LJS

Device Trade Name:	Duraspan™ Long-term Hemodialysis Catheter
Common Name:	Long Term Hemodialysis Catheter
Classification:	Sec 876.5540 Blood access device and accessories
510(k) Number:	K091506
Product Code:	MSD

Device Description

The Nylus™ PICC is a 5Fr, dual-lumen Peripherally Inserted Central Catheter. The Nylus PICC is a device intended to provide peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, central venous pressure monitoring and power injection of contrast media. The Nylus PICC is indicated for dwell times shorter or greater than 30 days.

The Nylus PICC is made from polyurethane and is approximately 60cm long. It has a reverse-tapered catheter design, with an injection-molded hub and extension lines with Luer Lock fittings for access attachment. Further, the Nylus PICC has been tested to withstand pressure injection at 5ml/sec with a maximum power injector pressure of 300psi. The catheter's interior and exterior surfaces have been modified by Semprus Sustain™ Technology.

The Semprus Sustain Technology is a proprietary biomimetic polymer surface modification intended to reduce platelet adhesion and thrombus accumulation. The Semprus Sustain Technology does not contain or release any active agents. *In vitro* and short term, i.e. 4-hour *in vivo* acute animal studies have demonstrated a reduction in adhered platelets and thrombus accumulation on the surface of the Nylus PICC when compared to an unmodified catheter. Preclinical *in vitro* and animal models do not necessarily predict clinical performance with respect to thrombus accumulation.

Indications for Use

The Nylus™ PICC is intended to provide peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, central venous pressure monitoring and power injection of contrast media. The Nylus PICC is indicated for dwell times shorter or greater than 30 days. The device has a maximum recommended infusion rating of 5mL/sec.

Rationale for Substantial Equivalence

As a PICC, the intended use of the Nylus PICC is equivalent to the predicate devices, Synergy™ CT PICC (K101329) and Zeus™ CT PICC (K083763). The Nylus PICC is equivalent to the predicate Zeus CT PICC and the Duraspan™ Long-term Hemodialysis Catheter in that each device has a biomimetic surface modification or coating.

The Nylus PICC is substantially equivalent to the predicate PICCs by intended use and design.

- The Nylus PICC is identical to the predicates in dimension, 5Fr, 60cm
- The Nylus PICC is identical to the predicates in configuration, dual lumen
- The Nylus PICC has the same underlying materials as the predicate, except for some colorants (color change is for brand identification)
- The Nylus PICC is sterilized via EO sterilization like the predicate Synergy CT PICC
- The Nylus PICC is identical to the predicates in labeling and physical properties. The maximum recommended infusion rating for power injection is 5mL/second. The maximum recommended pressure setting for power injection is labeled for a maximum of 300 psi.
- The Intended Use is identical to the predicates. They are all intended for use as PICCs. There is no change in the fundamental clinical intended use.

Summary of Safety and Effectiveness Data

Testing demonstrates that the Nylus PICC is as safe and effective as the predicate devices and meets all relevant consensus and FDA recognized standards. The test results in this submission demonstrate that the Nylus PICC meets the expected performance requirements for a PICC device, and is therefore substantially equivalent to the predicates relative to safety and

mechanical properties as a PICC. The ability of the Semprus Sustain Technology to reduce platelet adhesion and thrombus accumulation on the device surface was demonstrated in both *in vitro* and animal tests.

Characteristic	Results
Platelet Adherence	99% reduction in platelet adherence compared to unmodified catheter control in an *in vitro* 2-hour bovine blood flow loop
	Following 45 days of exposure to serum, 97% reduction in platelet adherence compared to predicate uncoated PICC in an *in vitro* 2-hour bovine blood flow loop
	Greater than 98% decrease in the attachment of platelets, lymphocytes, monocytes and polymorphs compared to the predicate uncoated PICC in an *in vitro* human blood flow model
Thrombus Accumulation	Greater than 99% decrease in thrombus weight accumulation compared to the unmodified control catheter in an *in vitro* 2-hour blood flow loop
	99% decrease in surface area of thrombus coverage compared to the predicate uncoated PICC in an *in vivo* 4-hr canine model

Conclusion

The Nylus PICC is substantially equivalent to predicate PICCs in terms of design and intended use. There is no difference in functionality as it relates to the PICC application. The Semprus Sustain surface modification, which is intended to reduce platelet adhesion and thrombus accumulation on the catheter surface, does not raise new questions of safety or effectiveness, as compared to the predicates. Therefore, the Nylus PICC is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 6, 2012

Semprus BioSciences Corporation
Mr. Gregory Haas
Vice President, Product Innovation and Strategy
One Kendall Square
Building 1400 West
Cambridge, Massachusetts 02139

Re: K113225
Trade/Device Name: Nylus™ PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: September 13, 2012
Received: September 14, 2012

Dear Mr. Haas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Anthony D. Watson
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.05 16:40:32 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113225

Device Name: Nylus™ PICC

Indications for Use:

The Nylus™ PICC is intended to provide peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, central venous pressure monitoring and power injection of contrast media. The Nylus PICC is indicated for dwell times shorter or greater than 30 days. The device has a maximum recommended infusion rating of 5mL/sec.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Nov 5, 2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113225